

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI**

HM COMPOUNDING SERVICES, LLC,)	
and HMX SERVICES, LLC,)	
)	Case No. 4:14-cv-01858 (JAR)
Plaintiffs,)	
)	JURY TRIAL DEMANDED
v.)	
)	
EXPRESS SCRIPTS, INC.,)	
)	
Defendant.)	

FIRST AMENDED COMPLAINT

COMES NOW, Plaintiffs HM Compounding Services, LLC and HMX Services, LLC, by and through undersigned counsel, and for their First Amended Complaint against Defendant Express Scripts, Inc., states as follows:

INTRODUCTION

1. Plaintiff HMC and its New York and New Jersey affiliated pharmacies is an independently-owned and closely-held holding company of various compounding pharmacies that provides custom-made medications to patients.¹ Defendant Express Scripts, Inc. (“ESI”) is the nation’s largest prescription benefit manager (“PBM”). Defendant ESI has engaged in a concerted and coordinated effort to exclude HMC and other independent compounding pharmacies from the relevant pharmacy services and prescription drug market, thereby reducing competition in that market, driving patients to Defendant ESI and other PBMs’ own specialty and mail-order pharmacies, and depriving patients of meaningful choice in and access to pharmacy services and prescriptions drugs.

¹ The terms “Plaintiff” and “HMC,” as used herein, refer to and include HM Compounding Services, LLC and all of its New York and New Jersey affiliated pharmacies, including HMX Services, LLC.

2. Defendant ESI effectuated the conspiracy by coercing physicians to stop prescribing prescription medications compounded by Plaintiff HMC and other independent compounding pharmacies; disseminating false and misleading information to patients and physicians regarding the safety and regulatory status of compound medications; imposing insurmountable administrative obstacles to obtaining reimbursement for compound prescription medications; ending insurance coverage for compound medications and/or their constituent drugs; improperly withholding reimbursements on prescriptions already filled and submitted to Defendant ESI by HMC and other independent compounding pharmacies; and unilaterally terminating Plaintiff HMC and other independent compounding pharmacies without cause and without appropriate notice.

3. Defendant ESI's concerted conduct is intended to put Plaintiff HMC and other independent pharmacies out of business, drive business to Defendant ESI and other PBMs' mail-order and specialty pharmacies, and to corner the relevant market for pharmacy services and prescription drugs, including compounded drugs.

4. Defendant ESI's concerted conduct has substantially harmed competition in the relevant market for pharmacy services and prescription drugs and has adversely affected the health of patients by depriving them of medications needed to treat their individual and specialized needs.

5. In addition, Defendant ESI's conduct has breached its duties and obligations as a fiduciary under the Employee Retirement Income Security Act of 1974 (29 U.S.C. §1001 *et seq.*) ("ERISA") and the regulations promulgated thereunder by the United States Department of Labor (29 C.F.R. §2560.503-1), with respect to prescription drug benefits managed under plans governed by ERISA or its claim procedures.

6. As a result, Plaintiff HMC is entitled to an injunction enjoining Defendant ESI from engaging in such unlawful conduct, as well as an award of monetary damages suffered by Plaintiff as a result of Defendant ESI's wrongful conduct, together with other appropriate legal and equitable relief.

PARTIES, JURISDICTION, AND VENUE

7. Plaintiff HMC brings this action, in part, pursuant to Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26, to recover treble damages, injunctive relief, and the costs of this suit, including reasonable attorneys' fees, for Defendant ESI's violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. Plaintiff HMC also brings this action, in part, pursuant to ERISA § 502, 29 U.S.C. § 1132 to recover benefits due HMC under the terms of plans governed by ERISA, to enforce HMC's rights under the terms of such plans, to clarify HMC's rights to future benefits under the terms of such plans, and to enjoin ESI's conduct in violation of ERISA.

8. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1331 and 28 U.S.C. § 1337 because Plaintiff HMC asserts claims arising under Section 1 of the Sherman Act, 15 U.S.C. § 15. Jurisdiction is also founded on 28 U.S.C. §1331 and 29 U.S.C. §1132(e) because, on information and belief, a substantial portion of the health plan claims asserted herein arise under ERISA and the regulations promulgated thereunder by the United States Department of Labor, including, without limitation, 29 C.F.R. §2560.503-1. This Court has jurisdiction over claims arising under state law pursuant to the Court's supplemental jurisdiction under 28 U.S.C. § 1367.

9. Venue is proper under Section 12 of the Clayton Act, 15 U.S.C. § 22, under 29 U.S.C. §1132(e)(2), and under 28 U.S.C. § 1391, in that the Defendant ESI resides in this District.

10. Plaintiff HM Compounding Services, LLC and its New York and New Jersey affiliated pharmacies is an independently owned, closely held holding company of various compounding pharmacies in the Eastern United States, including one of the largest compounding pharmacies in that region and New York City's first compounding pharmacy to be accredited by the Pharmacy Compounding Accreditation Board ("PCAB"). HM Compounding Services, LLC is a Delaware limited liability company with its principal location in Brooklyn, New York, and is composed of several members, one of which is HMX Holdings, Inc., a Delaware corporation. HM Compounding Services, LLC is thus a citizen of a number of states, including Delaware.

11. Plaintiff HMX Services, LLC, one of HM Compounding Services, LLC's affiliated pharmacies, is a New Jersey limited liability company wholly owned by HMCS Pharmacy Holdings, LLC, a Delaware limited liability company. HMCS Pharmacy Holdings, LLC is, in turn, wholly owned by HM Compounding Services, LLC. HMX Services, LLC is thus a citizen of a number of states, including Delaware.

12. HMC provides custom-made medications, i.e., compound medications, to numerous patients, including pediatric patients who cannot take pill versions of particular drugs, patients that cannot tolerate one or more ingredients in manufactured drugs, drugs that are no longer manufactured but are still determined to be safe and effective, and compounds for particular types of treatments, including pain management, dermatological specialties, bio-identical hormone replacement, sexual dysfunction and enhancement, compounds for autism, compounds for weight management, and compounds for veterinary use.

13. Defendant ESI is a Delaware corporation with its principal place of business in St. Louis, Missouri. ESI is a PBM providing integrated pharmacy benefit management services, including network pharmacy claims processing, home delivery pharmacy services and specialty

pharmacy benefit management, formulary management and medical and drug analysis services, to manage drug plans for health plans, among others. Upon information and belief, ESI is the nation's largest PBM filling annually more than 1.4 billion prescriptions nationwide.

14. Defendant ESI owns and operates a mail-order pharmacy that provides pharmacy services to patients throughout the country, including in the Eastern United States.

15. Defendant ESI also owns and operates various specialty pharmacies that provide pharmacy services to patients nationwide, including in the Eastern United States. These specialty pharmacies include, but are not limited to, Accredo Health Group, Inc. ("Accredo") and Freedom Fertility Pharmacy. Specialty pharmacies provide specialty pharmacy and related services for patients with certain complex and chronic health conditions. On information and belief, Freedom Fertility Pharmacy also provides compounding pharmacy services and compound medications to its patients.

CO-CONSPIRATORS

16. CVS Caremark Corp. ("CVSC"), is a foreign corporation with its principal place of business in Scottsdale, Arizona. Upon information and belief, CVSC is the nation's second largest PBM providing comprehensive prescription benefit management services for over 2,000 health plans nationwide. In addition, it operates a national retail pharmacy network with over 60,000 participating pharmacies as well as numerous specialty pharmacies and mail order pharmacies including specialty mail order pharmacies.

17. Optum Rx ("ORx"), is a foreign corporation with its principal office located in Eden Prairie, Minnesota. Upon information and belief, ORx is the third largest PBM in the United States, providing pharmacy benefit management services for more than 12 million people nationwide whose clients include UnitedHealth Group's growing health plan business.

18. Prime Therapeutics, LLC (“Prime”), is a foreign limited liability company with its principal place of business in Eagan, Minnesota. It is an independent pharmacy benefit manager owned by 13 not-for-profit Blue Cross and Blue Shield health plans, subsidiaries or affiliates of those plans that processes claims and delivers medicine to more than 25 million members nationwide. Among other things, it provides formulary development, has a specialty pharmacy and manages a home delivery service for patient medications.

19. On information and belief, the Co-conspirators each own and operate mail-order pharmacies that provide pharmacy services to patients throughout the country, including in the Eastern United States.

20. Various other individuals and entities, known and unknown, and not named in this Complaint, participated as co-conspirators in the violations alleged herein and performed acts and made statements in furtherance thereof. Such persons or entities include other PBMs and other persons or entities that stand to benefit from the elimination of compounding pharmacies from the pharmacy services and prescription drug market and with whom Defendant ESI, the Co-conspirators, and/or other PBMs have commercial relationships. Such persons or entities acted as co-conspirators and aided, abetted, or participated with ESI and the named Co-conspirators in the commission of the wrongful acts alleged in this Complaint.

BACKGROUND

Prescription Benefit Managers

21. PBMs administer the prescription pharmaceutical portion of healthcare benefit programs, which are typically purchased by a plan sponsor. As part of their functions, PBMs provide bundled services related to the administration of pharmaceutical benefits, including claims adjudication, formulary design, management and negotiation of branded drug rebates, management and negotiation of networks of retail pharmacies, review of drug utilization,

processing claims from pharmacies for payment, and the operation of specialty and home-delivery pharmacies such as mail-order pharmacies used to dispense medications directly to patients. Some chain pharmacies, such as CVS, have merged with PBMs. Since their inception, PBMs have become multi-billion dollar businesses.

22. In the United States, PBMs manage 95% of all prescription drugs covered by insurance. ESI, CVSC, ORx and Prime dominate the PBM-market in the United States with a market share of more than 80%. On information and belief, CVSC and Defendant ESI control drug plans for over 40 of the Fortune 50 companies and between 80 and 90 percent of the commercial employer market.

Compounding Pharmacies

23. Drug compounding is a practice in which a licensed pharmacist, a licensed physician, or in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Plaintiff HMC is an independent compounding pharmacy providing patients with medications tailored to their specific needs pursuant to and in accordance with the instructions provided by the patient's physician.

24. Compounding is an integral part of pharmacy, the science and technique of preparing and dispensing drugs and medicines, and has historically been recognized as a legal and vitally important core component of traditional pharmacy practice and services.

25. Millions of patients have unique health needs that over-the-counter drugs ("OTCs") and FDA-approved prescription medications cannot meet. For these patients, personalized medication solutions prescribed by licensed physicians and prepared by trained and licensed pharmacists are the only way to achieve the health benefits required by the patient as prescribed by their physician.

26. Unlike commercially available drugs, which are manufactured on a large-scale basis and are not alterable or specifically appropriate for a patient, compounding allows the medication to be tailored to the needs of the patient who, for whatever reason, cannot or should not take the mass-produced drug.

27. For example, if a patient is allergic to a particular ingredient in a commercially available product, the medication can be compounded without the ingredient. If a patient is unable to swallow a commercially available pill, a liquid form can be compounded. If a dosage is too strong for an infant, a lower dosage can be compounded. Flavors can be added to make the medicine more palatable for a child so that the child will take the medicine. Additives for topical creams can be used to prevent skin irritation. Nonessential ingredients such as gluten or dye can be eliminated. Topical creams enable a physician to treat a patient's pain at the site of the pain, often avoiding the need for oral or injected narcotic drugs which can result in dependency.

28. Both the Food and Drug Administration ("FDA") and New York State regulate the practice of drug compounding by pharmacists who compound medicines in the State of New York.

29. Without access to the compounded medications, those patients who require medications tailored to meet their individualized needs are denied the treatment needed to address their health situation.

30. Plaintiff HMC provides various compound prescription medications for which there are no commercially available alternatives. For instance, HMC works with physicians to compound healing skin creams for patients suffering from otherwise incurable scarring caused by Mohs surgery. Working with physicians, HMC compounds customizable creams for

individual patients containing the appropriate blend of antibiotics, tissue regeneration components, and other medicines to facilitate the healing process.

31. In recent years, compound medications have been prescribed in response to the FDA's 2012 mandate to seek alternatives to addictive opioid narcotics. Topical pain-management medicines compounded by HMC and other independent compounding pharmacies provide physicians with a critical tool to accomplish this objective. Such topical medications, which typically do not penetrate the bloodstream, facilitate delivery of the medicine to the desired location while allowing patients to reduce or avoid the use of oral narcotics that affect the entire body and can lead to opioid dependency and abuse.

32. HMC also compounds customizable sinus medicines deliverable directly to the site of sinus infections through a unique nebulizer device. This compound medication and associated nebulizer help curb overuse of antibiotics, accelerate healing time, and enable patients to avoid costly and painful surgical procedures.

33. Until recently, ESI routinely processed and approved claims for compound prescription medications submitted by HMC.

Relationship Between HMC and ESI

34. ESI contends that the parties' relationship is governed by a Pharmacy Provider Agreement entered into by and between ESI and Wholesale Alliance, LLC d/b/a Third Party Station on behalf of Plaintiff HMC (the "Provider Agreement"), pursuant to which HMC agreed to provide certain pharmacy services to ESI members in exchange for ESI's agreement to compensate HMC for those pharmacy services.

35. ESI's Network Provider Manual (the "Manual"), which sets forth various terms and conditions, purports to be incorporated by reference into the Provider Agreement.

36. The terms of the applicable Provider Agreement or Provider Agreements, and of the applicable Manual or Manuals, are non-negotiable and, upon information and belief, are identical for nearly every pharmacy in the country, including other independent compounding pharmacies. HMC was not permitted to negotiate, and in fact did not negotiate, any terms in the applicable Provider Agreement(s) or Manual(s).

37. During the time in which the Provider Agreement and Manual were purportedly in effect (prior to ESI's improper termination), whenever an ESI subscriber would come into HMC's pharmacy to have a prescription filled, HMC would electronically submit a claim to ESI for the prescription prior to filling the prescription.

38. Within seconds, ESI would respond to HMC's electronic claim submission by electronically transmitting information back to HMC regarding, among other things, the price ESI would pay HMC to fill the prescription in accordance with the parties' Agreement.²

39. ESI's communication to HMC of the amount it would pay HMC to fill the prescription constituted acceptance by ESI of the submitted claim.

40. HMC was charged a transaction fee for each electronic claim it submitted to ESI.

41. HMC filled and dispensed the prescription after the parties exchanged consideration (i.e., mutual agreement to accept the claim submitted for reimbursement).

42. Pursuant to the Agreement, ESI was required to pay or reimburse HMC for the prescriptions after they were dispensed.

43. ESI has not reimbursed HMC for thousands of claims filled pursuant to physician's scripts, causing HMC to suffer economic damages in an amount to be determined.

² The term "Agreement," as used herein, refers to the contract between HMC and ESI, including the applicable Pharmacy Provider Agreement(s) and Network Provider Manual(s).

ESI's Termination of HMC

44. On or about July 31, 2014, ESI sent a letter to HMC purporting to terminate HMC as a provider, effective September 1, 2014, pursuant to 4.2(c) of “the ESI Provider Agreement” and Appendix B of “the Provider Manual.” ESI quotes Appendix B as follows:

Immediate Termination. PBM shall have the right to immediately terminate this Agreement upon written notice to Network Provider in the event that . . . (v) any representation to PBM or any response to a question set forth on the Provider Certification is untrue or becomes untrue.

45. In the July 31, 2014 letter, ESI, based on purported statements from “multiple members”, claimed that HMC made misrepresentations to ESI regarding “waiver/reduction” of copayments. ESI did not provide HMC with an opportunity to cure.

46. HMC responded to ESI's letter on August 5, 2014. In its August 5 letter, HMC confirmed that “[i]t is the policy of HM Compounding (the “Provider”) to make a good-faith effort to collect patient co-payments from patients” and offered to address ESI's concerns.

47. Plaintiff HMC at all times complied with and performed its obligations under the Agreement.

ANTITRUST ALLEGATIONS

48. Defendant ESI and the Co-Conspirators combined, conspired, and engaged in a concerted effort to unreasonably restrain trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, *et seq.*, to end all coverage for compound prescription medications and eliminate Plaintiff HMC and other independent compounding pharmacies as competitors in the Relevant Market.

Trade and Interstate Commerce

49. The provision and sale of many of the the pharmaceutical services and products, and insurance coverage for such services and products related to HMC, are each in, and affect, interstate commerce.

50. Many of the activities of Defendant ESI and the Co-conspirators in administering and processing the prescription drug benefits for employers, unions, and health plans in every state are in the regular, continuous, and substantial flow of interstate commerce, and have a substantial effect upon interstate commerce.

51. Many of the acts in the conspiracy described herein between and among Defendant ESI and the Co-conspirators had, and continues to have, a direct, substantial and reasonably foreseeable impact on United States commerce.

The Relevant Market

52. The relevant service market affected by Defendant ESI and the Co-conspirator's conduct is pharmacy services that are reimbursed by insurance, including, but not limited to, the compounding, filling, and dispensing of prescription medications. The relevant product market affected by Defendant ESI and the Co-conspirator's conduct is prescription drugs that are reimbursed by insurance, including, but not limited to, compounded prescription drugs.

53. The relevant geographic market for activity that affects HMC is the Eastern United States, including, but not limited to, New York and New Jersey.

54. The unlawful conspiracy between Defendant ESI and the Co-conspirators has had the effect of unreasonably restraining, suppressing, and eliminating competition in the provision of pharmacy services and the dispensation of prescription drugs covered by insurance in all markets in which Plaintiff HMC did and could operate in interstate commerce.

Concerted Action by Defendant ESI and the Co-conspirators to Unreasonably Restrain Trade in the Relevant Market

55. Defendant ESI and the Co-conspirators combined, conspired, and agreed to unreasonably restrain trade in the Relevant Market by, among other actions, entering into a

horizontal agreement to boycott and/or refuse to deal with HMC and other, independent compounding pharmacies.

56. Upon information and belief, Defendant ESI and each of the Co-conspirators is an active member of the Pharmaceutical Care Management Association (“PCMA”), “the national association representing America’s pharmacy benefit managers (PBMs).” (*See* <http://www.pcmanet.org/about-pcma/about-pcma>; <http://www.pcmanet.org/aboutpcma/members>.)

57. Executives from Defendant ESI and each of the Co-conspirators serve on the PCMA’s Board of Directors: Jon Roberts (President, CVS/Caremark & Executive Vice President, CVS Health) is the Chairman of the PCMA Board of Directors and Eric Elliot (President & Chief Executive Officer, Prime Therapeutics), Tim Wicks (Chief Executive Officer, OptumRx), George Paz (Chairman & Chief Executive Officer, Express Scripts) are all members of the PCMA Board of Directors. (*See* <http://www.pcmanet.org/about-pcma/board-of-directors>.)

58. The PCMA’s website makes clear that the PCMA facilitates communication and collaboration among leaders in the PBM industry to “shape the industry’s direction” and “explore collaborative solutions” to industry issues, including, for example, “specialty pharmacy”:

- a) “PCMA’s members shape the industry’s direction and positions on a broad range of public policy issues that affect your business. No other trade group in America has more depth and influence on PBM issues.” (<http://www.pcmanet.org/about-pcma/members>.)
- b) “PCMA’s Membership includes PBM CEOs and other industry leaders. Becoming a PCMA Member puts you in touch with this motivated and influential group of leaders that is shaping the future of PBMs nationwide.” (<http://www.pcmanet.org/about-pcma/members>.)

- c) “PCMA provides one-of-a-kind conference events that bring together PBM industry leaders and their partners in pharmaceutical care to explore collaborative solutions to issues such as e-prescribing, specialty pharmacy, and Medicare Implementation.” (<http://www.pcmanet.org/about-pcma/members>.)

59. The PCMA hosts various meetings and summits at which PCMA members convene to discuss industry issues and strategies for addressing those issues.

60. Upon information and belief, Defendant ESI and the Co-conspirators joined together in approximately 2013—through the PCMA and otherwise—to study the market for compound prescription medications and compound medicine prescribing trends, and to collectively determine how to best eradicate coverage for compound medications in 2014.

61. Upon information and belief, after surreptitiously gathering information about physician prescribing trends and compound pharmacy dispensing practices, Defendant ESI and the Co-conspirators joined together to jointly exclude independent compounding pharmacies from the Relevant Market by employing various, anti-competitive means, including, but not limited to: intimidating physicians who prescribed compound medications and the patients who take them; effectuating insurmountable obstacles for pharmacies to receive reimbursement for compound prescriptions; eliminating coverage for all compound medications by denying coverage for the ingredients used to prepare them; terminating HMC and other independent compounding pharmacies from their respective networks without cause; and putting independent compounding pharmacies out of business.

62. The conduct of Defendant ESI and the Co-conspirators in excluding independent compounding pharmacies from the Relevant Market is only reasonable, explicable, or in the legitimate economic self-interests of the individual PBMs if it is the result of a conspiracy or agreement to jointly boycott HMC and independent compounding pharmacies.

63. If Defendant ESI or any of the Co-conspirators acted unilaterally to exclude compound prescription medications from its formulary or otherwise raise fees to account for the purported costs associated with compounded medicines, the services and formularies made available to plan sponsors by that individual PBM would be less competitive compared to those of ostensibly competing PBMs.

64. Only by agreeing to act in a concerted manner to uniformly exclude compound prescription medications from coverage would Defendant ESI and the Co-conspirators be able to exclude independent compounding pharmacies from the Relevant Market while simultaneously maintaining their respective spheres of control over the prescription drug benefit market.

Defendant ESI and the Co-conspirators Coerce Physicians to Stop Prescribing Medications Compounded by HMC and Other Independent Compounding Pharmacies

65. Defendant ESI and the Co-conspirators jointly initiated their plan to illegally deny patients coverage for compounded drugs through a series of concerted steps. Upon information and belief, in approximately 2013, Defendants began targeting independent compounding pharmacies through extensive and rigorous auditing processes. These audits were used to identify network providers that prescribe compounded medicines and the network providers that prepare them.

66. Upon information and belief, ESI used the data collected through these clandestine audits to identify doctors that prescribe compounded medicines and to target, intimidate, and coerce them to stop writing those prescriptions immediately or face accusations of fraud and abuse and/or termination of their provider agreements despite the fact that compound medicines were covered under those agreements.

67. Upon information and belief, those physicians were instructed to cease writing prescriptions for compound medications regardless of the individual patient's needs and

regardless of the prescribing physician's assessment of the treatment most effective for the individual patient.

68. Upon information and belief, Defendant ESI and the Co-conspirators circulated letters to physicians that prescribed compound medications containing false and misleading information regarding compound medications.

69. Upon information and belief, Defendant ESI and the Co-conspirators also contacted said physicians by telephone to communicate false and misleading information regarding compound medications (as set forth more fully herein) and to impliedly threaten said physicians with retaliation if they continued to prescribe compound medicines.

Defendant ESI and the Co-conspirators Disseminate False and Misleading Information Regarding Prescription Drugs Compounded by HMC and Other Independent Compounding Pharmacies

70. Upon information and belief, Defendant ESI and the Co-conspirators then began contacting patients directly by letter to inform them that their compound medicines would no longer be covered by their prescription benefit policies. Defendant ESI and the Co-conspirators included misleading statements about the patients' compound prescription medications in those letters.

71. For example, Defendant ESI sent letters to patients containing the following statements:

To help safeguard your health and protect you from taking medications that are not approved by the Federal Drug Administration (FDA), we periodically review your prescription drug claims history. . . . Compounded drugs may contain ingredients that are not FDA- approved for a specific condition and can be subject to quality and potency issues that can be a safety concern. Such compounded drug products are unproven, and are generally for experimental or investigational use . . . [Y]ou will need to replace your compounded prescription with a prescription for an FDA-approved product. This will protect your health . . . Please ask your doctor to prescribe an oral or topical FDA- approved product as an alternative to the compounded prescription.

72. ORx sent patients letters with the following statements:

Effective July 1, 2014, your compound medication prepared by your pharmacy is no longer covered under your pharmacy benefit plan because it contains a bulk chemical or ingredient that has not been approved by the U.S. Food and Drug Administration (FDA). Prescription Drug Products covered under your pharmacy benefit plan must be approved by the FDA. FDA-approved medications are available to treat conditions for which some doctors prescribe compound medications. (Emphasis in original.)

73. Upon information and belief, each of the Co-conspirators sent letters and/or had similar communications with patients. The statements contained in these letters and communications, however, are materially misleading and deceptive.

74. Under the Drug Quality and Security Act (“DQSA”), which was signed on November 27, 2013, certain sections of the Federal Food, Drug, and Cosmetic Act (“FDCA”) were modified. Under the revised Section 503A of the FDCA, compounding facilities are specifically *exempted* from sections of the FDCA relating to (1) compliance with current good manufacturing practices (“CGMP”) (§ 502(f)(1)); (2) labeling with adequate direction for use (§ 502(f)(1)); and (3) FDA approval prior to marketing (§ 505).

75. Despite these exemptions, Defendant ESI and the Co-conspirators have conspired to mislead patients and the public at large about how these federal regulations apply to compound medicine. Defendant ESI and the Co-conspirators have intentionally sent misleading letters in an effort to scare and dissuade patients from taking any compound medicines. Defendant ESI and the Co-conspirators’ misleading propaganda is intended to deceive the public and to steer them away from the treatment prescribed by their doctors.

76. Upon information and belief, Defendant ESI and each of the Co-conspirators have represented to patients that compound medicines are “experimental” and therefore unsafe because they are not “FDA approved”. However, Defendant ESI and the Co-conspirators failed to advise

those patients that all so-called “off-label” use is “experimental” and that PBMs continue to cover mass-produced off-label drugs, even though they are not proven safe and effective for an off-label purpose, because it is a generally accepted principal that off-label or “experimental” drug use is appropriate when prescribed by a licensed physician.

77. Further, PBMs mislead patients that they are protecting patients’ interests by rejecting all claims for drugs not approved for market by the FDA. But Defendant ESI and the Co-conspirators omitted from these communications the fact that compound medications are specifically exempted from that requirement under federal law because lawmakers recognize the important role such medications play in treating patients.

78. Defendant ESI and the Co-conspirators have further misled patients by asserting that compound medications are not safe because they have not gone through the FDA approval process. This statement is misleading because it omits the material fact that under federal law, such medications are exempt from the FDA approval process.

79. Defendant ESI and the Co-conspirators also failed to inform patients of the federal and state oversight measure that govern compound pharmacists to ensure proper compounding.

80. Under New York law,” [t]he practice of the profession of pharmacy is defined as the administering, preparing, **compounding**, preserving, or the dispensing of drugs, medicines and therapeutic devices on the basis of prescriptions or other legal authority. . . [.]” NY. Educ. Law § 6801 (emphasis added). A pharmacy in the State of New York is defined to mean “any place in which drugs, prescriptions, or poisons are possessed for the purpose of **compounding**, preserving, dispensing or retailing, **or in which drugs, prescriptions or poisons are compounded**, preserved, dispensed or retailed, or in which such drugs, prescriptions or poisons

are by advertising or otherwise offered for sale at retail.” N.Y. Educ. Law § 6802(1) (emphasis added). The practice of the profession of pharmacy, including compounding, is therefore specifically contemplated and regulated under the Education Law.

81. Further, the New York State Board of Pharmacy sets the standards that apply to drug compounding in the State of New York. (N.Y. Educ. Law § 6804.) Accordingly, federal regulation and state statutes and guidelines work in tandem to regulate how pharmacists prepare compound medications in the State of New York (and the other states in the union). Under this framework, the FDA does not and cannot approve compound medications because each medication is different and specifically designed to address each patient’s individualized health requirements and needs. However, all of the compound drug ingredients used by HMC are legal and deemed medically necessary by the prescribing physician.

82. By omitting this material information about compound medications, Defendant ESI and the Co-conspirators intended to scare, deceive, and steer patients away from the compound medications prescribed by their doctors. Upon information and belief, Defendant ESI and the Co-conspirators anticipated that these tactics would also deceive patients into not objecting to this offensive and improper change in coverage for prescription drug benefits. Defendant ESI and the Co-conspirators’ letters to patients were materially misleading and deceptive.

Defendant ESI and the Co-conspirators Knowingly Establish Insurmountable Obstacles to Obtaining Reimbursements for Prescription Medications Compounded by HMC and Other Independent Compounding Pharmacies

83. Upon information and belief, after gathering and reviewing compound medication prescribing data, Defendant ESI and the Co-conspirators quietly instituted a policy of requiring prior authorizations for compound medications that exceeded a threshold dollar amount, intentionally set to be an amount too low to cover most, if not all, compound medication claims.

84. Upon information and belief, Defendant ESI and the Co-conspirators continued to rigorously monitor and adjust that threshold amount to ensure that compound medication claims would categorically be denied coverage without any formal changes to the prescription drug plans managed by Defendant ESI and the Co-conspirators.

85. Defendant ESI and the Co-conspirators collectively took these actions as part of a concerted effort to change patients' prescription drug benefit coverage without being held accountable to patients, physicians, or pharmacies, and in violation of the laws intended to protect prescription benefit policy holders and all consumers in the State of New York.

86. Upon information and belief, Defendant ESI and the Co-conspirators each announced a formal plan to effectively eliminate coverage for compound medications managed by Defendant ESI and each of the Co-conspirators.

87. On May 30, 2014, CVSC announced a new policy in its provider manual related to copayment collection and claims for compounds. This co-payment collection policy marked a drastic change from CVSC's prior policy and required onerous steps intended to result in the rejection of all claims for compound medications.

88. Further, effective May 30, 2014, CVSC announced that compounders must include not only the NDC number of each ingredient used in a compound, but also "at least (2) scientifically valid studies in peer-reviewed journals supporting the clinical efficacy of the additional ingredients" for each ingredient and make those available for CVSC review upon request. CVSC knows this requirement is impossible to meet because of the lack of peer-reviewed medical literature on compound preparation and their individual ingredients at this time.

89. By implementing these policies, defendant CVSC has created administrative hurdles designed to deny coverage effective immediately for legitimate prescriptions and to prevent patients from getting the medications they need. Moreover, these hurdles have been applied only to compound medications, not other products being used for off-label purposes.

90. Similarly, on or about June 3, 2014, ESI launched its new “Compound Management Solution” and a formal campaign to inform providers that it would not pay claims for compound medications. Upon information and belief, ESI forced its “Solution” upon all clients to become effective either on July 15, 2014, or September 15, 2014, depending on the client’s administrative response to the announcement.

91. Upon information and belief, the “Solution” will eliminate the prior authorization option for compound medications and instead will “automatically reject” any claim for such medications. Further, effective September 15, 2014, ESI will no longer provide coverage for 1,000 compound ingredients to be identified on a “list” not yet provided. Thus, ESI has essentially announced that effective September 15, 2014, it would cut off its almost 40% market-share of prescription drug benefit reimbursement for all compound medications, except intravenous medicines.

92. ESI implemented its “Solution” to reduce its own spending and without considering the health and well-being of plan members.

93. Without coverage of the 1,000 compound ingredients targeted by ESI, and other bulk compound ingredients, HMC will not be able to fill the overwhelming majority of prescriptions for compound medications prescribed by physicians.

94. ORx has launched a similar attack. Upon information and belief, representatives from ORx have admitted to targeting the top 100 prescribers of compound medicines for

“discussions” about their prescribing practices, have begun excluding coverage for bulk compound ingredients, and have instituted policies to require and deny authorizations for any compound medication prescriptions.

95. ORx and other large PBMs have also imposed impossible requirements on compound pharmacies to remain network providers. For example, ORx has informed HMC (and presumably all other independent compounding pharmacies) that URAC accreditation is now required to provide network compounding services. URAC, an independent nonprofit accrediting organization, only certifies pharmacies that dispense FDA approved manufactured medications. It does not have an accreditation program for compounding pharmacies which only make compound medications tailored to the specific needs of the patient. When HMC contacted URAC to begin the accreditation process, HMC was told that there is no URAC certification program available for independent pharmacies that solely provide compound medication services.

96. ORx’s (and upon information and belief other PBMs) insurmountable obstacle that independent compounding pharmacies be URAC certified is yet another thinly-veiled ploy to eliminate independent compounding pharmacies from the market.

97. Upon information and belief, ORx is requiring this certification because it maintains a specialty pharmacy that qualifies for URAC certification under the umbrella of ORx’s other retail pharmacy services. In other words, while all independent compounding pharmacies will be precluded from dispensing and delivering compound medicines ORx (and the other PBMS) will continue to be able to deliver compound medications to patients by mail or other delivery services which are the same as those which would be used by HMC.

98. Requirements that compound medicines be FDA-approved and supported by peer-reviewed articles are requirements that are equally impossible to meet. Because compound medications are exempted from the FDA-approval process (which typically requires an investment of extremely large amounts into several billion dollars, in part, to fund the studies that generate the peer-reviewed literature), these requirements are simply an arbitrary and impossible barrier to coverage erected by the PBMs to eliminate compound medicines from the prescription benefit drug market.

99. There is no legitimate reason why HMC and other compounding pharmacies should be restricted from using the United States mail or other delivery services to deliver medicines to patients in the same manner utilized by Defendant ESI and the Co-conspirators. Upon information and belief, the reason Defendant ESI and the Co-conspirators have imposed the prohibition is to limit or eliminate competition from other pharmacies.

100. Through these concerted actions, Defendant ESI and the Co-conspirators have used their market power to eradicate compound prescription medications and pharmacy services from the Relevant Market—thus putting independent compounding pharmacies, like HMC, out of business.

ORx, CVSC, and ESI Terminate or Suspend Plaintiff HMC from Their Respective Networks.

101. Upon information and belief, as part of their unified plan to eliminate compound medicines, Defendant ESI and the Co-conspirators jointly began manufacturing unwarranted reasons to terminate and/or suspend independent compounding pharmacies' contracts in order to wrongfully avoid paying claims for compound medicines, even though those medicines were covered under the prescription benefit policies being managed by Defendant ESI and the Co-conspirators.

102. Upon information and belief, by collectively “auditing” independent compounding pharmacies, Defendant ESI and the Co-conspirators were able to terminate and/or suspend Pharmacy Provider Agreements with independent compounding pharmacies, including HMC, without providing notice to those pharmacies of any purported violations of the agreements and without being held accountable to the patients whose prescriptions were being affected by Defendant ESI and the Co-conspirators’ conduct.

103. As a result of such illegal conduct, HMC has not been reimbursed for thousands of prescriptions filled pursuant to physicians’ scripts, causing HMC to suffer economic damages in an amount to be determined.

ORx Terminates HMC from ORx’s network.

104. By Termination Letter dated March 3, 2014, ORx informed Third Party Station (“TPS”), a Third Party Administrator in ORx’s prescription benefit program, that HMC was being terminated as a network provider because the Pharmacy Network Agreement “prohibits delivering, shipping, mailing and/or dispensing Covered Prescription Services to members” and demanded that HMC cease and desist from engaging in such activity.

105. By letter dated March 17, 2014, attorneys for HMC responded to that Termination Letter, explaining that the contract provision cited by ORx did not prohibit “delivering, shipping” and/or “dispensing” prescription services to members, nor could it if it were to comply with governing legal and ethical requirements for these services under New York law. By letter dated May 29, 2014, ORx responded to that letter asserting that HMC’s contract was being terminated immediately “for cause” on the basis that the “Pharmacy understood that mailing, shipping and/or delivering of Covered Prescription Services is not allowed under the retail contract with ORx”

106. Dispensing medication by mail is a permitted practice under New York law and regulations and the restriction imposed by ORx contravenes public policy because it deprives insured patients of access to the pharmacy of their choice to obtain the compound medicines required for their health needs.

107. Subsequently, by letters dated June 25, 2014, ORx informed HMC that it was terminating “for cause” HMC’s New Jersey and New York compounding pharmacies’ Pharmacy Network Agreement with Wholesale Alliance TPS, LCC d/b/a Third Party Station for alleged “Fraud, Waste and Abuse” for purportedly engaging in “prescription splitting to obtain multiple dispensing fees, etc.” By letter dated July 16, 2014, HMC explained that it was not “splitting” prescriptions and receiving multiple dispensing fees and requested that the contract be reinstated until an appeal hearing on the issue was held. ORx denied that request, causing HMC significant money damages.

CVSC stops paying claims for compound medication prescriptions submitted by HMC.

108. By letter dated June 30, 2014, CVSC informed HMC of its “ongoing audit” of its pharmacy “covering the period of April 2013 through September 30, 2013.” That “ongoing audit” had not been previously disclosed to HMC. In that letter, CVSC informed HMC that “CVS Caremark is placing your pharmacy under payment and adjudication suspension” effective immediately based upon purported “compliance issues” identified in the ongoing audit. CVSC informed HMC that pursuant to this decision, HMC “may not submit claims to CVS Caremark for adjudication” and that “future cycle checks for prior claims will be withheld pending resolution of our audit review.” Accordingly, effective June 30, 2014, CVSC stopped paying claims submitted by HMC and precluded HMC from submitting any future claims.

109. By letter dated July 16, 2014, HMC addressed CVSC's stated audit concerns and requested that CVSC reinstate HMC. By letter dated July 28, 2014, CVSC denied HMC's request to reconsider the payment and adjudication suspense placed upon HMC. In that letter, CVSC admitted that it had begun a policy of rejecting compound prescriptions and requiring prior authorizations "based upon plan edits." No information about the "plan edits" was provided in CVSC's letter, nor were those "plan edits" disclosed to HMC prior to the termination letter. CVSC went on to state: "We do not believe that there is any patient harm with our decision to suspend payment and claims adjudication for HM Compounding" CVSC provided no support for this conclusion.

Defendant ESI terminates HMC from ESI's network.

110. By letter dated July 22, 2014, HMC informed ESI that HMC had become aware that ESI was directly notifying providers that they were not to continue prescribing compound medicines even if such prescriptions were in patients' best interest. In retaliation for HMC's complaint, ESI, just seven days later, on July 31, 2014, sent HMC a "notice of immediate termination" of HMC's Agreement with ESI. In its letter, ESI alleged that HMC had purportedly made material misrepresentations to ESI regarding collecting patients' co-payments and, as a result, was terminating HMC's contract immediately. Then, one day later, by letter dated August 1, 2014, ESI responded to HMC's July 22, 2014 letter. In that letter, ESI did not deny making such statements to prescribing physicians; rather, it took the position that ESI "has a legal right to communicate with providers regarding benefit coverage issues."

Defendant ESI and the Co-conspirators Implement a “No Mail Fulfillment” Requirement.

111. Defendant ESI and the Co-conspirators have also implemented a requirement that prohibits HMC from using the United States mail or other delivery services to deliver compound medications to patients.

112. Upon information and belief, there is no legitimate reason why HMC and other compounding pharmacies should be restricted from using the United States mail or other delivery services to deliver medicines to patients in the same manner utilized by Defendant ESI and the Co-conspirators.

113. Upon information and belief, the motive of Defendant ESI and the Co-conspirators in implementing the “no mail fulfillment” restriction and its application to other non-mail methods of delivery is to eliminate competition from HMC and other independent compounding pharmacies, by requiring patients who wish to receive their compound prescriptions by mail to obtain them only from the Defendant ESI or the Co-conspirators’ mail-order prescription programs.

114. Upon information and belief, and based on the timing and nature of the actions described herein, the Defendant ESI and Co-conspirators’ membership and active participation in the PCMA, the absence of incentives for unilateral action, and the facts more fully set forth herein, the Defendant ESI and the Co-conspirators coordinated their conduct in a concerted effort to eliminate competition by HMC and other independent compounding pharmacies in the Relevant Market.

The Effect of Defendant ESI and the Co-Conspirators’ Conduct

115. PBMs manage 95% of all prescription drugs covered by insurance and ESI, together with the Co-conspirators, control virtually the entire PBM market. Without the ability

to fill prescription for members of ESI and the Co-conspirators, HMC and other independent compounding pharmacies will be excluded from the Relevant Market and, thus, driven out of business. On information and belief, this is the goal of Defendant ESI and the Co-conspirators.

116. In addition to driving HMC and other independent compounding pharmacies out of the Relevant Market and out of business, Defendant ESI and the Co-conspirator's actions also deprive patients of the life-enhancing medications that they need to address their medical conditions and which have been prescribed for them by their doctors.

117. Defendant ESI and the Co-conspirators can do this because they control the market that purchases prescription drugs through employer-sponsored health insurance programs. By joining together to use their market power to control the drugs that physicians prescribe and to coerce physicians to prescribe less effective, mass-produced drugs to patients who are better served by specialty drugs, Defendant ESI and the Co-conspirators are driving out compound medicines and compound pharmacy services as market sub-classes in the prescription drug benefit and services market.

118. Defendant ESI and the Co-conspirators have engaged in this behavior to eliminate compound medicines and compounding pharmacy services from the Relevant Market so that ESI and the Co-conspirators' preferred mass-produced drugs will be prescribed and purchased, to the benefit of ESI and the Co-conspirators.

119. Defendant ESI and the Co-conspirators' efforts to switch patients from a compound medicine to a mass-produced drug is solely cost-driven by the PBMs and disregards the patients' medical and health requirements as determined by their physicians. In other words, the PBMs are driving patients to less costly and less effective medications which are not in the patients' best interest as determined by their doctors.

120. Defendant ESI and the Co-conspirators' actions are intentionally designed to both eliminate HMC and other compounding pharmacies as competitors in the Relevant Market and to force patients to accept less effective medication for their medical problems simply so that Defendant ESI and the Co-conspirators can make more money.

121. Upon information and belief, the conduct of Defendant ESI and the Co-conspirators is also designed to divert business from Plaintiff HMC and other independent compounding pharmacies to the specialty, mail-order, and compounding pharmacies owned, operated, or controlled by Defendant ESI and/or one or more of the Co-conspirators.

COUNT I
VIOLATION OF SECTION ONE OF
THE SHERMAN ACT, 15 U.S.C. § 1

122. Plaintiff HMC incorporates by reference as though fully set forth herein paragraphs 1 through 121 of the Complaint.

123. Defendant ESI has engaged in an unlawful contract, combination, or conspiracy with the Co-conspirators and others to unreasonably restrain trade and commerce in the Relevant Market in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

124. Defendant ESI and the Co-conspirators contracted, combined, and conspired to restrain trade in the Relevant Market by entering into a horizontal agreement or agreements to boycott and/or refuse to deal with Plaintiff HMC and other independent compounding pharmacies and/or otherwise exclude Plaintiff HMC and other independent compounding pharmacies from the Relevant Market and thus drive them out of business.

125. Defendant ESI and the Co-conspirators effectuated this boycott and/or refusal to deal by jointly engaging in conduct calculated to end insurance coverage for compound medicines and to drive independent compounding pharmacies out of business. The concerted

conduct of Defendant ESI and the Co-conspirators includes, but is not limited to, the following:

- a) coercing physicians to stop prescribing medications compounded by Plaintiff HMC and other independent compounding pharmacies with threats and accusations of fraud and abuse and/or termination of their provider agreements;
- b) knowingly disseminating false and misleading information regarding the safety and status of compound medications under federal and state regulations to patients in an attempt to induce said patients to cease purchasing medications compounded by Plaintiff HMC and other independent compounding pharmacies;
- c) knowingly creating insurmountable obstacles to obtaining reimbursements from Defendant ESI and the Co-conspirators for compound medications;
- d) ending coverage for medications compounded by Plaintiff HMC and other independent compounding pharmacies under prescription drug plans managed by Defendant ESI and the Co-conspirators;
- e) refusing to reimburse Plaintiff HMC for thousands of compound prescription claims submitted to Defendant ESI; and
- f) unilaterally terminating Plaintiff HMC and other independent compounding pharmacies from the networks of Defendant ESI and the Co-conspirators without cause.

126. Defendant ESI and the Co-conspirators' concerted refusal to deal with and/or boycott of Plaintiff HMC and independent compounding pharmacies constitutes a *per se* unreasonable restraint on trade in the Relevant Market under Section 1 of the Sherman Act, 15 U.S.C. §1, because *inter alia*:

- a) it is a horizontal agreement between Defendant ESI and the Co-conspirators, all of whom are PBMs and operate at the same level of the prescription drug benefit market;
- b) it excludes Plaintiff HMC and other independent compounding pharmacies from obtaining access to reimbursements from health insurance and plans for prescription medications—a supply, facility, or market necessary for Plaintiff HMC and other independent compounding pharmacies to compete in the pharmaceutical services and prescription drug market;

- c) Defendant ESI and the Co-conspirators possess a dominant position in the prescription drug benefit market—PBMs manage 95% of all prescription drugs covered by insurance and Defendant ESI and the Co-conspirators dominate the PBM-market in the United States with a market share of more than 80%—and because of this dominant position, Defendant and the Co-conspirators are able to and in fact do exercise control over and/or substantially affect the purchase and sale of pharmaceutical services and prescription drugs in the Relevant Market; and
- d) the concerted conduct of Defendant ESI and the Co-conspirators is not justifiable by plausible arguments that it was intended to enhance overall efficiency and make the Relevant Market more competitive; in fact, said conduct has destroyed competition in the Relevant Market, as described more fully herein.

127. In addition, the concerted conduct of Defendant ESI and the Co-conspirators has had a substantial and continuing anticompetitive effect on the Relevant Market in the following, but not limited to the following, ways:

- a) eliminating compounding pharmacy services and compound medications from the Relevant Market;
- b) substantially decreasing the output and/or supply of pharmaceutical services and prescription drugs in the Relevant Market;
- c) depriving patients of meaningful choice in and access to pharmaceutical services and prescription drugs in the Relevant Market;
- d) depriving patients of medically-necessary pharmaceutical services and prescription drugs in the Relevant Market;
- e) reducing or eliminating the prescription of compound medications by physicians in the Relevant Market;
- f) diverting patients away from Plaintiff HMC and other independent compounding pharmacies to Defendant ESI and the Co-conspirators' various mail-order and specialty pharmacies that are in competition with Plaintiff HMC and other independent compounding pharmacies in the Relevant Market, including, but not limited to, Accredo, Freedom Fertility Pharmacy, and Express Scripts Pharmacy, among others; and
- g) hindering innovation, price-competition, and patient choice in the delivery of pharmaceutical services and prescription drugs in the Relevant Market by imposing and maintaining high barriers to entry and participation

therein.

128. As a direct and proximate result of Defendant ESI and the Co-conspirators' concerted conduct, Plaintiff HMC has been and will continue to be irreparably injured and financially damaged in its business and property in that, among other things, Plaintiff HMC has suffered and will continue to suffer significant lost revenue and net profits from the substantial decrease in reimbursements from compound medicines covered by health insurance policies and plans. In addition, Plaintiff has not received reimbursements for thousands of prescriptions already filled and submitted to Defendant ESI. Plaintiff HMC's damages, the amount of which will be determined at trial, are subject to trebling, pursuant to Section 4 of the Clayton Act.

129. The damages Plaintiff HMC has sustained from its exclusion as a competitor from the Relevant Market constitutes an injury of the type the Sherman Act was designed to prevent and was directly caused by that which makes Defendant ESI and the Co-conspirators' conduct unlawful under the Sherman Act.

130. Plaintiff has no adequate remedy at law from its injury and damages alleged herein.

WHEREFORE, Plaintiff HMC hereby respectfully requests that judgment be entered in its favor and against Defendant, Express Scripts, Inc., and that this Court enter an Order:

- a) preliminarily and permanently enjoining Defendant Express Scripts, Inc. from engaging in anticompetitive and illegal conduct in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, as more fully described in Count XIV herein;
- b) awarding Plaintiff HMC compensatory damages in an amount to be determined at trial;
- c) awarding Plaintiff HMC three times actual damages against Defendant Express Scripts, Inc. for its violations of Section 1 of the Sherman Act;
- d) awarding Plaintiff HMC interest, attorney's fees, and costs incurred herein; and

- e) awarding such other and further relief as this Court deems just and proper under the circumstances.

COUNT II
VIOLATION OF NEW YORK ANTITRUST LAW
SECTION 340 OF THE NEW YORK GENERAL BUSINESS LAW

131. Plaintiff HMC incorporates by reference as though fully set forth herein paragraphs 1 through 130 of the Complaint.

132. New York General Business Law § 340.1 provides:

Every contract, agreement, arrangement or combination whereby

A monopoly in the conduct of any business, trade or commerce or in the furnishing of any service in this state, is or may be established or maintained, or whereby

Competition or the free exercise of any activity in the conduct of any business, trade or commerce or in the furnishing of any service in this state is or may be restrained or whereby

For the purpose of establishing or maintaining any such monopoly or unlawful interference with free exercise of any activity in the conduct of any business, trade or commerce or in the furnishing of any service in this state any business, trade or commerce or furnishing of any service is or may be restrained, is hereby declared to be against public policy, illegal and void.

133. Thus, Section 340 of New York's General Business Law makes illegal and void any contract, arrangement, combination or agreement that restrains competition in any business, or unlawfully interferes with the free exercise of any activity in the conduct of any business.

134. PBMs provide prescription drug management services to 95% of the patients covered by prescription drug benefit insurance in the United States. Defendant ESI and the Co-conspirators collectively control the vast majority of that market share.

135. Defendant ESI and the Co-conspirators have joined together to use their market share to negatively control and eliminate the consumption of compound medications in the Relevant Market, or to effectively eliminate the supply of compound medications in the Relevant Market and to put independent compounding pharmacies out of business.

136. Defendant ESI and the Co-conspirators' actions have an adverse effect on competition as a whole, by among other things, forcing physicians to prescribe inferior medicines for patients' particular conditions, or forcing them to forego participating in-network, by forcing patients to take inferior medicines or be denied the prescription drug benefit coverage to which they are entitled, and by forcing independent compounding pharmacies out of business.

137. Because they have joined together to effectively ban or boycott compound medicines, Defendant ESI and the Co-conspirators have committed a per se violation of New York's antitrust laws.

138. Alternatively, as described above, Defendant ESI and the Co-conspirators' actions have had an adverse effect on competition as a whole, by, among other things:

- a) forcing physicians to either limit patient access to the treatment that the physicians have determined best suits the patient's interest or be denied access to the health insurance policies and plans that provide coverage for prescription medications;
- b) eliminating compounding pharmacy services and compound medications from the Relevant Market;
- c) substantially decreasing the output and/or supply of pharmaceutical services and prescription drugs in the Relevant Market;
- d) depriving patients of meaningful choice in and access to pharmaceutical services and prescription drugs in the Relevant Market;
- e) depriving patients of medically-necessary pharmaceutical services and prescription drugs in the Relevant Market;
- f) reducing or eliminating the prescription of compound medications by physicians in the Relevant Market;
- g) diverting patients away from Plaintiff HMC and other independent compounding pharmacies to Defendant ESI and the Co-conspirators' various mail-order and specialty pharmacies that are in competition with Plaintiff HMC and other independent compounding pharmacies in the Relevant Market, including, but not limited to, Accredo, Freedom Fertility Pharmacy, and Express Scripts Pharmacy, among others; and

- h) hindering innovation, price-competition, and patient choice in the delivery of pharmaceutical services and prescription drugs in the Relevant Market by imposing and maintaining high barriers to entry and participation therein.

139. Defendant ESI is liable to Plaintiff HMC for the damages that Plaintiff HMC has suffered as a result of ESI's actions, the amount of such damages to be determined at trial, plus attorneys' fees. Such damages are subject to trebling pursuant to General Business Law § 340.

WHEREFORE, Plaintiff HMC hereby respectfully requests that judgment be entered in its favor and against Defendant, Express Scripts, Inc., and that this Court enter an Order:

- a) preliminarily and permanently enjoining Defendant Express Scripts, Inc. from engaging in anticompetitive and illegal conduct in violation of the Donnelly Act, § 340 of the New York General Business Law, as more fully described in Count XIV herein;
- b) awarding Plaintiff HMC compensatory damages in an amount to be determined at trial;
- c) awarding Plaintiff HMC three times actual damages against Defendant Express Scripts, Inc. for its violations of the Donnelly Act;
- d) awarding Plaintiff HMC its interest, attorney's fees, and costs incurred herein; and
- e) awarding such other and further relief as this Court deems just and proper under the circumstances.

COUNT III
ERISA § 502(a)(1)(B), 29 U.S.C. § 1132(a)(1)(B)

140. Plaintiff HMC incorporates by reference as though fully set forth herein paragraphs 1 through 139 of the Complaint.

141. HMC, as an ERISA beneficiary, brings this count pursuant to ERISA § 502(a)(1)(B), 29 U.S.C. § 1132(a)(1)(B), to recover benefits due HMC under the terms of plans governed by ERISA, to enforce HMC's rights under the terms of such plans, or to clarify HMC's rights to future benefits under the terms of such plans.

142. ESI administers and manages the prescription drug benefit components of various employer and employee-organization sponsored plans that provide participants with medical benefits, or benefits in the event of sickness, accident, disability, or death and various group health plans. On information and belief, these plans are Employee Welfare Benefit Plans within the meaning of 29 U.S.C. § 1002(1) and/or are covered by the ERISA claims procedures pursuant to the Patient Protection and Affordable Care Act, 42 U.S.C. § 300gg-19(a)(2)(A) (referred to hereinafter collectively as the “ERISA Plans”).

143. With respect to claims for compound medications submitted by HMC to ESI for reimbursement, ESI transmits an electronic message back to HMC containing various pieces of information, including an “Ins. Id.” number and a “Grp.” number. Based on the foregoing, and on information and belief, HMC was and is an ERISA “beneficiary” with respect to the ERISA Plans pursuant to 29 U.S.C. § 1002(8) because *inter alia* HMC has the right to directly receive the benefits of its patients who are participants in the ERISA Plans pursuant to the terms of those plans.

144. Indeed, ESI has paid HMC directly (rather than HMC patients/plan participants) for compound prescription medication claims submitted to ESI.

145. ESI was at all relevant times a fiduciary under the ERISA Plans because ESI exercised discretionary authority and control when paying prescription drug claims with Plan assets. *See* 29 U.S.C. § 1002(21)(A)(i).

146. In addition, ESI was at all relevant times a fiduciary under the ERISA Plans insofar as ESI exercised discretionary authority and control over the administration and management of the ERISA Plans. *See* 29 U.S.C. § 1002(21)(A)(iii). Such discretionary authority and control includes, but is not limited to, the following:

- a) deciding which drugs should be included in or excluded from its standardized formularies and, in addition, deciding which drugs to add or delete from the standardized formularies that are part of the ERISA Plans; and
- b) adjudicating (i.e., deciding to pay or deny) claims for prescription medications submitted by claimants under the ERISA Plans.

147. On information and belief, ESI was at all relevant times the plan and/or claims administrator for the prescription drug components of the ERISA Plans, either because the plan documents designated ESI as such or because ESI in fact exercised its discretion in adjudicating individual claims for prescription drug benefits under the ERISA Plans.

148. The ERISA claims procedures, set forth in 29 C.F.R. § 2560.503-1, establish the minimum requirements imposed on ESI, as a plan and/or claims administrator, with respect to benefit determinations under the ERISA Plans.

149. With respect to any adverse benefit determination, ESI was required to provide HMC, as an ERISA beneficiary and claimant, with a written or electronic notification setting forth, in a manner calculated to be understood by HMC, the following information:

- a) The specific reason or reasons for the adverse determination;
- b) Reference to the specific ERISA Plan provisions on which the determination is based;
- c) A description of any additional material or information necessary for the claimant to perfect the claim and an explanation of why such material or information is necessary;
- d) A description of the ERISA Plan's review procedures and the time limits applicable to such procedures, including a statement of the claimant's right to bring a civil action under section 502(a) of the Act following an adverse benefit determination on review;
- e) In the case of an adverse benefit determination made pursuant to a group health plan or a plan providing disability benefits:
 - i) If an internal rule, guideline, protocol, or other similar criterion

was relied upon in making the adverse determination, either the specific rule, guideline, protocol, or other similar criterion; or a statement that such a rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination and that a copy of such rule, guideline, protocol, or other criterion will be provided free of charge to the claimant upon request; or

- ii) If the adverse benefit determination is based on a medical necessity or experimental treatment or similar exclusion or limit, either an explanation of the scientific or clinical judgment for the determination, applying the terms of the plan to the claimant's medical circumstances, or a statement that such explanation will be provided free of charge upon request.
- f) In the case of an adverse benefit determination by a group health plan concerning a claim involving urgent care, a description of the expedited review process applicable to such claims.

See 29 C.F.R. § 2560.503-1(g).

150. On information and belief, in or about June, 2014, ESI, as part of its “Compound Management Solution” exercised its discretionary authority and control over the administration and management of the ERISA Plans by excluding approximately 1,000 compound ingredients from the formularies that are part of the ERISA Plans. Those ingredients are necessary for the making of compounded prescription medications.

151. On information and belief, beginning in or about June, 2014, and continuing to the present, ESI implemented its “Compound Management Solution” by automatically rejecting all claims for compound prescription medications submitted by HMC, in its capacity as an ERISA beneficiary, for reimbursement under the ERISA Plans.

152. Each time such a claim was submitted for reimbursement, ESI transmitted an electronic, computer-generated notification to HMC indicating that the claim is or was “Rejected,” accompanied by perfunctory description, such as:

- a) “70 Product/Service Not Covered Drug NDC is not covered by the insurance”; or

- b) “7Y Compounds Not Covered”; or
- c) “MR Product Not On Formulary”.

The ESI computer-generated “Rejection” notifications for claims submitted by HMC routinely contained the foregoing, or substantially similar, language.

153. On information and belief, ESI did not transmit by any other method the information required by the ERISA claims procedures to HMC or the participants whose claims for compounded prescription medications were denied.

154. ESI’s computer-generated “Rejection” notifications are in violation of the ERISA claims procedures because *inter alia*:

- a) They do not provide a specific reason or reasons for the adverse determination;
- b) They do not reference the specific ERISA Plan provisions on which the determination is based;
- c) They do not provide a description of any additional material or information necessary for the claimant to perfect the claim and an explanation of why such material or information is necessary;
- d) They do not provide a description of the ERISA Plan’s review procedures and the time limits applicable to such procedures, which should include a statement of the claimant’s right to bring a civil action under section 502(a) of the Act following an adverse benefit determination on review;
- e) In the case of adverse benefit determinations under group health plan or a plan providing disability benefits:
 - i) Where an internal rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination, ESI’s notification did not provide the specific rule, guideline, protocol, or other similar criterion; nor did it provide a statement that such a rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination and that a copy of such rule, guideline, protocol, or other criterion will be provided free of charge to the claimant upon request; or

- ii) Where the adverse benefit determination was based on a medical necessity or experimental treatment or similar exclusion or limit, ESI's notification did not provide either an explanation of the scientific or clinical judgment for the determination, applying the terms of the plan to the claimant's medical circumstances, or a statement that such explanation will be provided free of charge upon request.
- f) Where the adverse benefit determination was made by a group health plan concerning a claim involving urgent care, ESI's notification did not provide a description of the expedited review process applicable to such claims.

See 29 C.F.R. § 2560.503-1(g).

155. ESI's violation of the ERISA claims procedures, and/or its failure to assert appropriate grounds for non-payment, are a waiver of all potential defenses to payment.

156. ESI's decision to deny coverage for compound prescription medications on claims submitted by HMC was, on information and belief, contrary to plan documents, arbitrary and capricious, and otherwise improper.

157. Upon information and belief, ESI has also denied claims for "vested" benefits in violation of ERISA, insofar as it has denied, and continues to deny, claims for compound medications that were and continue to be covered by ERISA Plans that do not grant discretionary authority to an administrator, like ESI, to unilaterally alter plan benefits.

158. Participants of the ERISA Plans who are patients of HMC and whose claims for compound medicines are denied suffer immediate and irreparable harm in that (a) they are being deprived of the beneficial and medically necessary prescription medications under the ERISA Plans and (b) they are being deprived of the procedural safeguards established by the ERISA claims procedures.

159. HMC suffers immediate and irreparable harm because it is a compounding pharmacy and derives a substantial percentage of its revenue from reimbursements from ESI for

compound medications.

160. HMC has exhausted all administrative remedies for each claim submitted to and denied by ESI for compound medications. Alternatively, the administrative remedies on such claims are deemed exhausted as a matter of law because ESI's claims procedures pursuant to which such claims were denied failed to comply with ERISA claims procedures and/or ESI failed to follow claims procedures that were consistent with the requirements of ERISA. In addition, any further appeals from ESI's denial of claims for compound prescription medications would have been futile because ESI had a blanket policy of categorically denying all such claims.

161. There is no adequate remedy at law for Plaintiff's injuries alleged herein.

WHEREFORE, Plaintiff HMC hereby respectfully requests that judgment be entered in its favor and against Defendant, Express Scripts, Inc., and that this Court enter an Order:

- a) declaring that HMC is entitled to reimbursement for compound medication claims submitted to Express Scripts, Inc. pursuant to the ERISA Plans and that Express Scripts, Inc. has violated the ERISA Plans in refusing to reimburse Plaintiff HMC for such claims;
- b) preliminarily and permanently enjoining Defendant Express Scripts, Inc. from denying claims for compound medications submitted by HMC under the ERISA Plans unless and until Express Scripts, Inc. complies with ERISA and its accompanying regulations in adjudicating such claims;
- c) ordering Defendant Express Scripts, Inc. to make payments, and to continue rendering payments, for claims submitted by HMC for compound medications under the ERISA Plans, unless and until Express Scripts, Inc. renders claim decisions for the ERISA Plans in accordance with ERISA and its accompanying regulations;
- d) preliminarily and permanently enjoining Defendant Express Scripts, Inc. from denying claims submitted by HMC for compound medications pursuant to ERISA Plans for which such benefits have vested;
- e) awarding Plaintiff HMC interest, attorney's fees, and costs incurred herein; and

- f) awarding such other and further relief as this Court deems just and proper under the circumstances.

COUNT IV
ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3)

162. Plaintiff HMC incorporates by reference as though fully set forth herein paragraphs 1 through 161 of the Complaint.

163. HMC, as an ERISA beneficiary, brings this count pursuant to ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), to enjoin ESI's acts and/or practices that violate 29 U.S.C. § 1104 and/or the terms of the applicable ERISA Plans, and to obtain other appropriate equitable relief to redress such violations or to enforce the such provisions.

164. As an ERISA fiduciary, ESI was at all relevant times obligated to discharge its duties with respect to the ERISA Plans:

- a) solely in the interests of the participants and beneficiaries;
- b) for the exclusive purpose of: (i) providing benefits to participants and their beneficiaries; and (ii) defraying reasonable expenses of administering the plans; and
- c) with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent man acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims

See 29 U.S.C. § 1104(a)(1).

165. ESI breached its fiduciary duties by *inter alia*:

- a) ending coverage for certain compound ingredients under the ERISA Plans for the sole purpose of furthering reducing ESI's spending and expenses, and without considering the health and well-being of ERISA Plan participants or beneficiaries;
- b) violating the ERISA claims procedures in its adjudication of claims submitted by HMC; and
- c) knowingly disseminating false and misleading information regarding the safety and status of compound medications under federal and state

regulations to ERISA Plan participants and beneficiaries and to physicians administering care to such participants and beneficiaries.

166. HMC, an ERISA beneficiary, has suffered and will continue to suffer immediate and irreparable harm as a direct result of ESI's breach of its fiduciary duties because HMC is a compounding pharmacy and derives a substantial percentage of its revenue from reimbursements from ESI for compound prescription medications.

167. There is no adequate remedy at law for Plaintiff's injuries alleged herein.

WHEREFORE, Plaintiff HMC hereby respectfully requests that judgment be entered in its favor and against Defendant, Express Scripts, Inc., and that this Court enter an Order:

- a) declaring that Express Scripts, Inc.'s activities identified in this Count constitute a violation of its fiduciary duties under 29 U.S.C. § 1104;
- b) preliminarily and permanently enjoining Defendant Express Scripts, Inc. from eliminating from coverage those chemicals, drugs, and other ingredients used by HMC and other compounding pharmacies in the preparation of compound medications prescribed by licensed physicians for their patients who have prescription drug benefit coverage administered by Defendant Express Scripts, Inc. pursuant to an ERISA Plan and which had heretofore been covered by such plans;
- c) awarding Plaintiff HMC interest, attorney's fees, and costs incurred herein; and
- d) awarding such other and further relief as this Court deems just and proper under the circumstances.

COUNT V
DECEPTIVE TRADE PRACTICES: VIOLATION OF
SECTION 349 OF THE NEW YORK GENERAL BUSINESS LAW

168. Plaintiff HMC incorporates by reference as though fully set forth herein paragraphs 1 through 167 of the Complaint.

169. New York General Business Law ("GBL") § 349 prohibits any business or person from engaging in deceptive business practices in the conduct of any business, trade or commerce or in the furnishing of any service in New York state.

170. As alleged herein, through written and oral communications, Defendant ESI has engaged in material deceptive or misleading business practices targeting and affecting New York consumers, including purchasers and prescribers of compound medications, in violation of GBL § 349. Defendant ESI's deceptive or misleading business practices alleged herein are likely to mislead, and have misled, prescribing physicians, reasonable purchasers of compound medications, including New York consumers, and independent compounding pharmacies.

171. These representations and/or omissions of fact were misleading in a material way because they were likely to mislead reasonable physicians to believe that they must stop prescribing medically necessary compound medications or be subjected to allegations of fraudulent and abusive prescribing practices, even though compounding is recognized under federal and state law as an essential pharmacy function and even though the prescription of such medicines by a treating physicians is not an act of fraud or abuse. Defendant ESI used these tactics to deprive patients, including New York residents/consumers, from access to medically appropriate and necessary compound medications.

172. These representations and/or omissions of fact were also likely to mislead patients, including New York residents/consumers, into believing that compound medicines are not recognized as medically necessary or appropriate treatments under federal and state law, when, in fact, they are.

173. Defendant ESI deliberately made these material representations while omitting key facts about compound medications to steer physicians and patients away from using such medications (even though those medications are deemed by prescribing physicians to be medically necessary under the circumstances) and to prevent HMC from dispensing compound

medications, which has negatively impacted all consumers of prescription drugs covered by Defendant ESI in the State of New York.

174. Defendant ESI's violation of GBL § 349 has caused HMC to suffer injury including, *inter alia*, payments for prescription drugs that should have been covered under patients' health insurance policies and/or plans and, in addition, ESI's violation GBL § 349 deprived patients—including New York residents/consumers—of access to medically necessary compound medications.

175. Defendant ESI willfully and knowingly engaged in the conduct alleged herein.

176. Defendant ESI's conduct was morally culpable and constitutes a willful or wanton negligence or recklessness. Accordingly, HMC is entitled to damages, including treble damages, punitive damages, injunctive relief, and attorneys' fees pursuant to New York GBL § 349.

WHEREFORE, Plaintiff HMC hereby respectfully requests that judgment be entered in its favor and against Defendant, Express Scripts, Inc., and that this Court enter an Order:

- a) preliminarily and permanently enjoining Defendant Express Scripts, Inc. from engaging in deceptive and illegal trade practices in violation of Section 349 of the New York General Business Law, as more fully described in Count XIV herein;
- b) awarding Plaintiff HM Compounding Services, LLC compensatory damages in an amount to be determined at trial, trebled pursuant to New York GBL § 349;
- c) awarding Plaintiff HMC punitive damages against Defendant Express Scripts, Inc.;
- d) awarding Plaintiff HMC interest, attorney's fees, and costs incurred herein; and
- e) awarding such other and further relief as this Court deems just and proper under the circumstances.

COUNT VI
VIOLATION OF NEW JERSEY ANY WILLING PROVIDER
LAWS, N.J.S.A. §§ 17B:26-2.1i, 17B:27-46.1i

177. Plaintiff HMC incorporates by reference as though fully set forth herein paragraphs 1 through 176 of the Complaint.

178. Defendant ESI's improper termination of HMC from its networks without cause, and the provisions of the Agreement providing for such termination without cause, violate the Any Willing Provider Laws of the State of New Jersey.

179. New Jersey's Any Will Provider Laws prohibit group and individual health insurers providing benefits for pharmacy services, prescription drugs, or for participation in a prescription drug plan from refusing to contract with a pharmacy provider so long as the pharmacy meets the terms and conditions of the plan. Specifically, N.J.S.A.17B:26-2.1i provides, in pertinent part, as follows:

[N]o individual health insurance policy which provides benefits for pharmacy services, prescription drugs, or for participation in a prescription drug plan, shall be delivered, issued, executed or renewed in this State, or approved for issuance or renewal in this State on or after the effective date of this act, unless the policy .
..

* * *

Provides that no pharmacy or pharmacist shall be denied the right to participate as a preferred provider or as a contracting provider, under the same terms and conditions currently applicable to all other preferred or contracting providers, if the policy provides for coverage by contracted or preferred providers for pharmaceutical services, provided the pharmacy or pharmacist is registered pursuant to R.S.45:14-1 et seq., and accepts the terms and conditions of the policy

N.J. Stat. Ann. § 17B:26-2.1i(a)(2).

180. On information and belief, Defendant ESI manages pharmacy services, and/or prescription drug benefits of various group and/or individual health insurance plans delivered, issued, executed, renewed, or approved for issuance or renewal in the State of New Jersey.

181. HMC, through HMX Serices, LLC, is registered and licensed to provide pharmacy services in the State of New Jersey and does in fact provide pharmacy services to patients in that State.

182. Plaintiff HMC has accepted the terms and conditions of the Agreement between HMC and ESI.

183. ESI's termination of HMC from ESI's network without cause is a violation of New Jersey's Any Willing Provider Laws, N.J.S.A. §§17B:26-2.1i, 17B:27-46.1i, insofar as said termination denies HMC the right to participate as a preferred provider or as a contracting provider in ESI's pharmacy network.

184. As a direct and proximate result of ESI's violation of New Jersey's Any Willing Provider Laws, Plaintiff HMC has suffered and will continue to suffer significant and irreparable damages, including, but not limited to, lost revenue and net profits from the substantial decrease in reimbursements for compound medications covered by insurance.

WHEREFORE, Plaintiff HMC hereby respectfully requests that judgment be entered in its favor and against Defendant, Express Scripts, Inc., and that this Court enter an Order:

- a) preliminarily and permanently enjoining Defendant Express Scripts, Inc. from terminating Plaintiff HMC from Express Scripts' networks with respect to claims submitted under group and/or individual health insurance plans delivered, issued, executed, renewed, or approved for issuance or renewal in the State of New Jersey;
- b) awarding Plaintiff HMC compensatory damages in an amount to be determined at trial;
- c) awarding Plaintiff HMC interest, attorney's fees, and costs incurred herein; and
- d) awarding for such other and further relief as this Court deems just and proper under the circumstances.

COUNT VII
BREACH OF CONTRACT

185. Plaintiff HMC incorporates by reference as though fully set forth herein paragraphs 1 through 184 of the Complaint.

186. The Agreement between Plaintiff HMC and Defendant ESI was at all times and remains, a valid contract supported by adequate consideration.

187. Plaintiff HMC has performed its obligations under the Agreement.

188. Appendix A of the Manual requires ESI to provide HMC ninety (90) days' notice prior to termination of the Agreement with respect to HMC's business of dispensing covered medications to ESI members of an HMO, Insurer, or Carrier licensed under New Jersey law:

To the extent Provider provides services, including dispensing Covered Medications, to Members of an HMO, Insurer, or Carrier licensed under New Jersey law (and as such terms are defined by New Jersey law; collectively and/or individually, the "Sponsor") Provider agrees that the Provider Agreement is hereby amended, as required by and as consistent with law, so that the following rules and requirements are included and shall apply with respect to those services provided to Members of the Sponsors.

* * *

If the Provider Agreement is terminated, PBM shall give Provider at least ninety (90) days prior written notice. In the event of termination, Provider has the right, within ten (10) days of receipt of notice, to request a hearing. The foregoing shall not apply when the termination is based on non-renewal of the Provider Agreement, a determination of fraud, breach of the Provider Agreement by the Provider, or the opinion of the medical director of the Sponsor that the Provider represents an imminent danger to a patient or the public health, safety and welfare. (N.J.A.C. 11:24-15.2(b)1.i.).

(PBM Provider Manual, Appx. A, at 172) (emphasis added).

189. ESI breached the Agreement with HMC by terminating HMC without cause, terminating HMC without providing the requisite notice, and terminating HMC without providing an opportunity to cure.

190. As a direct and proximate result of ESI's unilateral termination of HMC without cause, proper notice, or an opportunity to cure, Plaintiff HMC has suffered and will continue to

suffer significant damages, including, but not limited to, lost revenue and net profits from the substantial decrease in reimbursements for compound prescription medications covered by health insurance policies and/or plans, the inability to locate alternative revenue sources to replace (or partially replace) the substantial revenue lost from ESI's improper termination of the Agreement, and inability to recover reimbursements for thousands of prescriptions already filled and submitted to Defendant ESI.

WHEREFORE, Plaintiff HMC hereby respectfully requests that judgment be entered in its favor and against Defendant, Express Scripts, Inc., and that this Court enter an Order:

- a) preliminarily and permanently enjoining Defendant Express Scripts, Inc. from terminating Plaintiff HMC from Express Scripts' networks;
- b) awarding Plaintiff HMC compensatory damages in an amount to be determined at trial;
- c) awarding Plaintiff HMC interest, attorney's fees, and costs incurred herein; and
- d) awarding for such other and further relief as this Court deems just and proper under the circumstances.

COUNT VIII
**BREACH OF THE IMPLIED COVENANT OF
GOOD FAITH AND FAIR DEALING**

191. Plaintiff HMC incorporates by reference as though fully set forth herein paragraphs 1 through 190 of the Complaint.

192. The law implies a covenant of good faith and fair dealing into the terms of the Agreement between HMC and ESI.

193. Defendant ESI breached the covenant of good faith and fair dealing when ESI terminated HMC on July 31, 2014 without cause, without giving HMC the required notice, and without providing HMC an opportunity to cure.

194. As a direct and proximate result of Defendant ESI's actions in breaching the implied covenant of good faith and fair dealing, HMC has suffered and will continue to suffer significant damages, including, but not limited to, lost revenue and net profits from the substantial decrease in reimbursements for compound prescription medications covered by health insurance policies and/or plans, the inability to locate alternative revenue sources to replace (or partially replace) the substantial revenue lost from ESI's improper termination of the Agreement, and inability to recover reimbursements for thousands of prescriptions already filled and submitted to Defendant ESI.

WHEREFORE, Plaintiff HMC hereby respectfully requests that judgment be entered in its favor and against Defendant, Express Scripts, Inc., and that this Court enter an Order:

- a) preliminarily and permanently enjoining Defendant Express Scripts, Inc. from terminating Plaintiff HMC from Express Scripts' networks;
- b) awarding Plaintiff HMC compensatory damages in an amount to be determined at trial;
- c) awarding Plaintiff HMC interest, attorney's fees, and costs incurred herein; and
- d) awarding for such other and further relief as this Court deems just and proper under the circumstances.

COUNT IX
TORTIOUS INTERFERENCE WITH A
BUSINESS EXPECTANCY

195. Plaintiff HMC incorporates by reference as though fully set forth herein paragraphs 1 through 194 of the Complaint.

196. Plaintiff HMC had a valid and reasonable business expectancy in the continued sale of compound medications to patients in the Eastern United States, including but not limited to, New York and New Jersey.

197. Defendant ESI knew and was aware of Plaintiff HMC's expectancy.

198. Defendant ESI intentionally interfered with Plaintiff HMC's valid and reasonable business expectancy in the following, but not limited to the following, ways:

- a) coercing physicians to stop prescribing medicines compounded by Plaintiff HMC and other independent compounding pharmacies with threats and accusations of fraud and abuse and/or termination of their provider agreements;
- b) knowingly disseminating false and misleading information regarding the safety and status of compound medications under federal and state regulations to patients in an attempt to induce said patients to cease purchasing medicines compounded by Plaintiff HMC and other independent compounding pharmacies;
- c) knowingly creating insurmountable obstacles to obtaining reimbursements from Defendant ESI and the Co-conspirators for compound medicines;
- d) ending coverage for medicines compounded by Plaintiff HMC and other independent compounding pharmacies under prescription drug plans managed by Defendant ESI;
- e) refusing to reimburse Plaintiff HMC for thousands of compound prescription claims submitted to Defendant ESI; and
- f) unilaterally terminating Plaintiff HMC and from ESI's networks without cause.

199. Defendant ESI was not justified in interfering with, and used improper means to interfere with, Plaintiff HMC's expectancy.

200. Defendant ESI's tortious interference was intentional, wanton, willful, outrageous, deliberate, done with an evil motive, and in reckless disregard for and indifference to the interests and rights of Plaintiff HMC and HMC's patients, thus warranting an award of punitive damages in an amount to be determined at trial.

201. As a direct and proximate result of Defendant ESI's intentional interference, Plaintiff HMC has suffered and will continue to suffer significant damages, including, but not limited to, lost revenue and net profits caused by the substantial decrease in reimbursements for compound prescription medications covered by health insurance policies and/or plans.

WHEREFORE, Plaintiff HMC hereby respectfully requests that judgment be entered in its favor and against Defendant, Express Scripts, Inc., and that this Court enter an Order:

- a) awarding Plaintiff HMC compensatory damages in an amount to be determined at trial;
- b) awarding Plaintiff HMC punitive damages against Defendant Express Scripts, Inc.;
- c) awarding Plaintiff HMC interest, attorney's fees, and costs incurred herein; and
- d) awarding such other and further relief as this Court deems just and proper under the circumstances.

COUNT X
DECLARATORY RELIEF

202. Plaintiff HMC incorporates by reference as though fully set forth herein paragraphs 1 through 201 of the Complaint.

203. An actual, valid, and justiciable controversy now exists between HMC and ESI as to the ability of the ESI to unilaterally terminate HMC without cause.

204. Certain provisions in the Provider Agreement and Manual purport to grant ESI the right to terminate HMC without cause. For instance, § 4.2.a of the Provider Agreement provides:

4.2.a **Without Cause.** This Agreement may be terminated by ESI without cause upon at least thirty (30) days written notice to Provider (or such longer period as may be required by law), with such termination effective at the end of such notice period.

205. In addition, the Section 2 of the "Termination" provision contained in Appendix B of the Manual provides:

2. **Without Cause.** This Agreement may be terminated by either party without cause upon at least thirty (30) days written notice to the other party, with such termination effective at the end of such thirty (30)-day notice period.

206. The foregoing termination provisions, and any other such provisions contained in the Agreement between HMC and ESI, are procedurally unconscionable as applied to the termination of HMC in that *inter alia*:

- a) ESI, as the largest PBM in the United States with significant control over the prescription benefit drug market, possessed grossly disproportionate bargaining power relative to HMC;
- b) the Provider Agreements are contracts of adhesion in that the terms of those agreements, including the termination provisions, are presented to pharmacies, like HMC, on a “take it or leave it basis,” such that HMC had no meaningful opportunity to, and in fact did not, negotiate the terms thereof; and
- c) Given ESI’s control over the prescription benefit drug market, HMC was economically compelled to accept ESI’s terms in order to participate in that market.

207. The foregoing termination provisions, and any other such provisions contained in the Agreement between HMC and ESI, are substantively unconscionable as applied to the termination of HMC in that *inter alia*:

- a) Given ESI’s control over the prescription benefit drug market, the termination provisions render HMC dependent on ESI;
- b) To the extent the provisions are interpreted to only grant ESI (and not HMC) the right to terminate the Agreement without cause, the entire risk of unilateral termination is allocated to HMC; and
- c) The terms are unduly burdensome to HMC to the extent they permit unilateral termination by ESI without permitting HMC an opportunity to recoup its investments in becoming and operating as a provider in ESI’s network.

208. Plaintiff HMC seeks a judgment pursuant to 28 U.S.C. § 2201 declaring that any termination without cause provisions contained in the Agreement between HMC and ESI—including, to the extent they apply, § 4.2.a of the Provider Agreement and Section 2 of the Termination section contained in Appendix B of the Manual—are severable from the remainder of the parties’ Agreement and void as unconscionable with respect to the termination of HMC.

209. The declaratory relief HMC seeks is necessary and proper at this time in order to clarify the duties, obligations, and rights of the parties, and to avoid the harm HMC will suffer if ESI is permitted to unilaterally terminate HMC without cause.

210. Plaintiff HMC has no adequate remedy at law.

WHEREFORE, Plaintiff HMC hereby respectfully requests that judgment be entered in its favor and against Defendant, Express Scripts, Inc., and that this Court enter an Order:

- a) Declaring that any termination without cause provisions contained in the Agreement between HMC and Express Scripts, Inc.—including, to the extent they apply, § 4.2.a of the Provider Agreement and Section 2 of the Termination section contained in Appendix B of the Manual—are severable from the remainder of the parties' Agreement and void as unconscionable with respect to the termination of HMC;
- b) awarding Plaintiff HMC interest, attorney's fees, and costs incurred herein; and
- c) awarding such other and further relief as this Court deems just and proper under the circumstances.

COUNT XI
PRELIMINARY AND PERMANENT INJUNCTION

211. Plaintiff HMC incorporates by reference as though fully set forth herein paragraphs 1 through 210 of the Complaint.

212. Plaintiff HMC has sustained, and will continue to sustain, irreparable injuries caused by ESI's conduct set forth herein.

213. Plaintiff HMC has no adequate remedy at law for the injuries and damages proximately caused by ESI's conduct.

214. Plaintiff HMC is likely to succeed on the merits of all of its claims against ESI.

215. Plaintiff is entitled to a preliminary and permanent injunction prohibiting Defendant ESI from:

(a) Eliminating from coverage those chemicals, drugs and other ingredients used by Plaintiff HMC and other compounding pharmacies in the preparation of compound medications prescribed by licensed physicians for their patients who have prescription drug benefit coverage administered by Express Scripts, Inc. pursuant to a health insurance program and/or plan and which had heretofore been covered by such insurance program and/or plan;

(b) Refusing to process and pay claims for payment submitted by HMC for compound medications prescribed by physicians for their patients who have prescription drug benefits administered by Express Scripts, Inc.;

(c) Enforcing a requirement which prohibits HMC from using the United States Postal Service or other delivery service to deliver to patients the compounded medications prescribed by their physicians;

(d) Denying prescription drug benefit coverage for prescriptions for compound medications prescribed by licensed physicians and who have prescription drug benefit coverage which is administered by Express Scripts, Inc.; and

(e) Ordering Express Scripts, Inc. to reinstate in full force and effect nunc pro tunc the Network Pharmacy Agreement dated September 5, 2012, entered into by and between HMC and Wholesale Alliance TPS, LLC d/b/a Third Party Station on behalf of Third Party Payer ESI and ordering payment of all rejected compound medicine claims on those policies.

WHEREFORE, Plaintiff HMC hereby respectfully requests that judgment be entered in its favor and against Defendant, Express Scripts, Inc., as follows:

- a) An order preliminarily and permanently enjoining Defendant Express Scripts, Inc. from making false and/or misleading statements regarding the safety and efficacy of compound medications; directing Defendant Express Scripts, Inc. to send corrective notices to patients and physicians regarding the safety and efficacy of compound medications; and processing and paying claims for the compound medications prescribed by physicians for the patients to the same extent and the same manner as provided prior to Defendant Express Scripts, Inc.'s false and misleading statements;
- b) An order preliminarily and permanently enjoining Defendant Express Scripts, Inc. from eliminating from coverage those chemicals, drugs, and other ingredients used by HMC and other compounding pharmacies in the preparation of compound medications prescribed by licensed physicians for their patients who have prescription drug benefit coverage administered by Defendant Express Scripts, Inc. pursuant to a health insurance program and/or ERISA Plan and which had heretofore been covered by the patient's insurance and/or ERISA Plan;

- c) An order preliminarily and permanently enjoining Defendant Express Scripts, Inc. from denying or otherwise refusing to process and pay claims for payment submitted by HMC for compound medications prescribed by physicians for their patients who have prescription drug benefits administered by Defendant Express Scripts, Inc.;
- d) An order preliminarily and permanently enjoining Defendant Express Scripts, Inc. from enforcing a requirement which prohibits HMC from using the United States Postal Service or other delivery service to deliver to patients the compound medications prescribed by their physicians;
- e) An order preliminarily and permanently enjoining Defendant Express Scripts, Inc. from denying or otherwise refusing to process and pay claims for compound medications submitted by HMC under the ERISA Plans unless and until Express Scripts, Inc. complies with the ERISA and its accompanying regulations in adjudicating such claims;
- f) preliminarily and permanently enjoining Defendant Express Scripts, Inc. from denying claims submitted by HMC for compound medications pursuant to ERISA Plans for which such benefits have vested;
- g) An order preliminarily and permanently enjoining Defendant Express Scripts, Inc. from terminating Plaintiff HMC from Express Scripts' networks with respect to claims submitted under group and/or individual health insurance plans delivered, issued, executed, renewed, or approved for issuance or renewal in the State of New Jersey;
- h) An order preliminarily and permanently enjoining Defendant Express Scripts, Inc. to reinstate in full force and effect nunc pro tunc the Network Pharmacy Agreement dated September 5, 2012, entered into by and between HMC and Wholesale Alliance TPS, LLC d/b/a Third Party Station on behalf of Third Party Payer Express Scripts, Inc. and ordering payment of all rejected compound medication claims on that agreement;
- i) An order awarding Plaintiff HMC interest, attorney's fees, and costs incurred herein; and
- j) An order awarding such other and further relief as this Court deems just and proper under the circumstances.

JURY DEMAND

Pursuant to RULE 38(b) of the FEDERAL RULES OF CIVIL PROCEDURE, Plaintiffs HM Compounding Services, LLC and HMX Services, LLC demand a trial by jury as to all claims and all issues properly so triable.

Respectfully submitted,

LEWIS, RICE & FINGERSH, L.C.

Dated: December 1, 2014

By: /s/ Winthrop B. Reed, III
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing was filed on December 1, 2014 with the Clerk of Court via the Court's CM/ECF system for electronic service on all counsel of record.

/s/ Winthrop B. Reed, III